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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,212	04/05/2001	Ying-Fei Wei	1488.1280006	3523
28730	7590	10/20/2003	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			O HARA, EILEEN B	
			ART UNIT	PAPER NUMBER

1646

DATE MAILED: 10/20/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/826,212

Applicant(s)

WEI ET AL.

Examiner

Eileen O'Hara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 117-220 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 117-220 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>22</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 5, 2003 has been entered.

Status of Claims

2. Claims 117-220 are pending and under examination in the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 118 and 119 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record in Paper No. 19.

Claims 118 and 119 are indefinite because claim 117 encompasses an isolated polypeptide comprising amino acids 1 to 233 of SEQ ID NO: 2, and dependent claims 118 and 119 encompass the polypeptide of claim 117, *further* comprising amino acids -25 to 233 and amino acids -26 to 233, respectively, of SEQ ID NO: 2, so that it is not clear if the polypeptide comprises the original amino acids 1 to 233 of SEQ ID NO: 2, and additionally also comprises amino acids -25 to 233 of SEQ ID NO: 2 (or -26 to 233), which would contain a large

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duplication, or if it only comprises the additional amino acids of -25 to -1 (-26 to -1) of SEQ ID NO: 2.

Applicants traverse the rejection and assert that the transitional language of claims 118 and 119 clearly indicates that the claimed polypeptides must include, in addition to amino acids 1-233 of SEQ ID NO: 2, amino acids -25 to -1 of SEQ ID NO: 2 (claim 118) or amino acids -16 to -1 of SEQ ID NO: 2 (claim 119).

Applicants' arguments have been fully considered but are not deemed persuasive. Because of the word "further", the claims encompass polypeptides that comprise a duplication of amino acids 1-233 of SEQ ID NO: 2. The rejection would be withdrawn if the word "further" was deleted from the claims.

Priority Determination

35 U.S.C. § 119(e) states that:

An application for patent filed under section 111(a) or section 363 of this title for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in a provisional application filed under section 111(b) of this title, by an inventor or inventors named in the provisional application, shall have the same effect, as to such invention, as though filed on the date of the provisional application filed under section 111(b) of this title, if the application for patent filed under section 111(a) or section 363 of this title is filed not later than 12 months after the date on which the provisional application was filed and if it contains or is amended to contain a specific reference to the provisional application.

4. Applicant is advised that the instant application can only receive benefit under 35 U.S.C. § 119 from an earlier application which meets the requirements of 35 U.S.C. § 112, first paragraph, with respect to the now claimed invention. Provisional application No. 60/035,496 does not meet the requirements of 35 USC § 101 and § 112, since the protein of SEQ ID NO: 2 as disclosed in that application did not have any specific and substantial utility, or a well

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established utility, as determined according to the current Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday, January 5, 2001. Because the provisional application No. 60/035,496 does not meet the requirements of 35 U.S.C. § 112, first paragraph, for those reasons given below, it is therefore unavailable under 35 U.S.C. § 119. The effective priority date of the instant application is considered to be the filing date of provisional application 60/054,885, August 7, 1997, because the claimed invention was not enabled in parent application 60/035,496.

Provisional Application No. 60/054,885 discloses the protein of SEQ ID NO: 2 and shows experiments in which the soluble form of the protein prevents induction of apoptosis by binding the ligand TRAIL. Although provisional application No. 60/035,496 discloses the same protein, there is no ligand or activity for the protein disclosed.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 117-220 are rejected under 35 U.S.C. 102(e) as being anticipated by Ashkenazi et al., US Patent Application Publication No.2002/0161202, effective filing date June 18, 1997 (08/878,168).

Claims 117-220 encompass isolated polypeptide of SEQ ID NO: 2 (encoded by the cDNA clone contained in ATCC Deposit No. 97788), produced by a eukaryotic host cell, further comprising a heterologous polypeptide which may be a human immunoglobulin Fc region, and composition comprising the polypeptide and a carrier.

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Ashkenazi et al. discloses a protein named Apo-2DcR (SEQ ID NO: 1) that is identical to the protein of SEQ ID NO: 2 of the instant application (see attached sequence alignments).

Ashkenazi et al. also teach that the protein can be recombinantly produced by eukaryotic host cells (paragraphs 0088, 00093, 0096, 0104, 0109, 0120-0129), the protein fused to a heterologous protein which may be an immunoglobulin sequence which may be human (paragraphs 0021, 0152, 0157-0164), and compositions comprising protein and a carrier (paragraphs 0204-0205, 0260-0261). Therefore, Ashkenazi et al. anticipates the claims.

Conclusion

6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

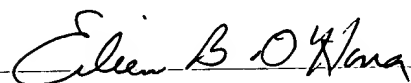
Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.



Patent Examiner